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VALIDATING ALTERNATIVE THERAPIES: ADD-ADHD STUDY DESIGNS

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Dr. Lappin has designed and conducted trials of an experimental pulsed magnetic therapy for migraine headaches and multiple sclerosis and recently completed a large-scale project to measure patient perceptions of acupuncture techniques and outcomes. She was the coproducer of the 1999 conference "Helping Kids with ADD: Alternative Approaches to Optimal Health" and is the copublisher of a quarterly newsletter of the same name. She is trained in neurofeedback, a technique used to treat thousands of children with ADD, and has consulted with the University of Washington on research designs for alternative treatments of this disorder. Dr. Lappin has coauthored several journal articles and conference presentations on research design and clinical trials of alternative therapies and recently received a research grant from the National Institutes of Health (NIH) to continue her work in this area. Dr. Lappin is currently assisting The Monroe Institute to develop NIH grant proposals. She is also organizing a second conference on "Helping Kids with ADD," to be held October 14 at George Mason University in Fairfax, Virginia.

Introduction

The goal of most applied research projects is to demonstrate that a particular treatment or intervention works. If someone has personally experienced or observed the effectiveness of the treatment this is an easy task. Anecdotal data will be sufficient to confirm what they already "know." Most of the time, however, we are interested in persuading a larger, often more skeptical audience that a product or treatment has value. What is required for this task is a success story that (a) clearly spells out the who, what, when, where, and why of the successful intervention, and (b) provides a strong basis for concluding that the treatment or intervention of interest, not some other factor, was responsible for the observed improvement. The purpose of this paper is to help practitioners/researchers design studies that will accomplish this. I am going to focus specifically on evaluating Hemi-Sync® interventions in children and adults with attention deficit disorder (ADD) or attention deficit hyperactivity disorder (ADHD). However, the principles that will be covered are applicable to studies in any population.

Designing and conducting convincing studies requires that we think through our objectives in advance, curb our inclination to "go with the flow" instead of sticking to a treatment protocol,

and keep detailed, meticulous records. This is difficult even for people with years of scientific training, so it's understandable that people who simply want to experience, enjoy, and share Hemi-Sync might shy away from such a daunting task. So why, then, do we encourage you to incorporate research into your practice? The answer is easy—the benefits to clients, practitioners, and the Institute are tremendous. Good studies can uncover new applications for Hemi-Sync and point to ways of improving upon what we are currently doing. They can identify the people most likely and least likely to benefit, and the ways in which the power of the tapes and technology The Monroe Institute offers can be enhanced. Good studies are also invaluable for spreading the word. Well-written journal articles open doors within the wider professional community and also open markets in public and private sector organizations. In short, good research is good business, and it's good for people. And once you get the hang of it, it can be gratifying and even fun.

There are all kinds of research designs. Here, we will discuss four: qualitative case studies; single-subject and small-group time-series designs; single-group comparative studies; and multiple-group controlled studies. We will illustrate each design with a published study that employed the Hemi-Sync technology.

Case Studies

Two fundamental factors determine the value of a study: the relevance, comprehensiveness, and accuracy of the details provided (the who, what, when, where, and why); and the investigator's ability to support cause-effect arguments by ruling out alternative explanations for positive results. Establishing causality is the domain of controlled studies; exploring and documenting novel uses of a technology is the province of case studies. The difference between a scientifically worthless anecdote and a valuable case study lies primarily in the level of detail reported and the richness of the description.

The elements of a good case study include

- WHO: Basic demographics of subject (e.g., age, sex, occupation), subject's medical history (diagnosis, presenting problem, symptoms), and the nature and results of any prior treatments
- WHAT: Details of the specific treatment used in the study
- WHEN: When the treatment was administered, how long, how often
- WHERE: Treatment setting (e.g., home, school, office)
- WHY: Rationale for the treatment selected
- OUTCOME: Detailed description of the results

Qualitative Case Studies

Case studies can be either qualitative or quantitative, depending on the way the results are measured and reported. In complex cases where patients have multiple diagnoses and/or exhibit a variety of symptoms, the practitioner often does not know in advance exactly what symptoms or conditions may be ameliorated by the treatment. When this is the case, the qualitative approach is most appropriate; i.e., you describe the patient's condition and symptoms in rich detail, both before and after the intervention.

Dr. Suzanne Morris's case studies of children treated with Hemi-Sync for oral feeding problems exemplify this approach. For example, in describing an autistic child's response to his initial exposure to Metamusic® tapes (Morris 1998), Dr. Morris says, ". . . he accepted touch to his hands and chest, initiated eye contact and smiling, and appeared to be calm and peaceful." After the tapes were incorporated into an intensive week-long, sensory-based treatment program, the child "continued to show increased interaction and eye contact, began to explore toys, imitated his body movements and facial expressions in a mirror, . . . gagging and vomiting ceased." These descriptions are compelling because they describe specific behaviors, they are relevant to the presenting problem (rejecting food), and they accurately depict the variety of changes observed.

Case studies will never convince the scientific community that a certain strategy or intervention really works. This is fine because that is not the purpose of a case study. The purpose of a case study is to alert fellow practitioners and researchers to new possibilities—new ways of treating complex, difficult-to-treat patients, new conditions or symptoms that might be amenable to the treatment, and new ways of combining treatments. If others obtain similar results, eventually someone will be bold enough to see whether the results stand up in a controlled trial. If they do, the scientific and medical communities will finally pay attention.

Single-Subject and Small-Group Time-Series Designs

Quantitative case studies are different from qualitative case studies in that they generally focus on a single outcome and include some kind of numerical measurement of that outcome over time. The paper by Brill and Walker (1985) illustrates a quantitative case study. They begin with a detailed description of the subject, the presenting problem and the treatment setting, and then proceed to describe the nature and results of the subject's earlier conventional treatment. Documenting the results of earlier treatments is valuable because it can demonstrate that improvements associated with the Hemi-Sync intervention are not simply a result of someone paying attention to the problem. Finally, the authors describe the Hemi-Sync intervention they used and display quantitative results in a graph. Their graph tracks the number of days each week the subject engaged in at least one episode of self-injurious behavior. The results are quite convincing because the data are objective, and they show a

clear trend over time—self-injurious behavior continued throughout the conventional treatment period, then dropped off sharply during the Hemi-Sync period, and stayed at the zero incident level for a year after discharge from a residential unit. When data are collected across multiple time periods like this, you have a time-series design.

Collecting time-series data is an excellent strategy in small, single-group studies as well as in case studies. James Thomas, PhD (1988), was able to show that Hemi-Sync contributed to reduction of behavioral incidents in a small sample of seriously emotionally disturbed adolescent girls because he collected behavioral incident reports for eight weeks prior to the intervention as well as during the eight weeks of intervention. Suzanne Morris, PhD (1998), also used a time-series design in her pilot study of developmentally disabled children with oral feeding problems. She not only collected pre-intervention baseline data for four to six sessions, she also collected data during two to four control sessions in which subjects heard music that did not contain Hemi-Sync sounds. Thus, she could draw more definitive conclusions about the importance of Hemi-Sync tones by comparing results to both the baseline and the soothing music treatment periods.

As the studies above illustrate, if you can hypothesize in advance what outcome is most likely to be affected, it is extremely useful to devote time prior to treatment to finding a good measure of that outcome, and to obtain pretreatment baseline data. Without baseline data showing that the condition or outcome was stable prior to the intervention, and/or follow-up data showing that the outcome returned to its previous level after the treatment was withdrawn, it is very difficult to convince others that the target intervention was responsible for the observed changes.

Single-Group Comparative Studies

Another approach that is especially useful in exploratory studies is a comparison of the effects of two or more treatments in a single group of subjects. This type of study is sometimes called a crossover design because subjects “cross over” from one treatment condition to the other.

Robert Sornson’s evaluation (1999) of the tape preferences of children with attention deficit disorder (ADD) is a good example of this approach. Sornson recruited eighteen children, aged six to fourteen years, all of whom had been diagnosed with ADD. The subjects were asked to listen to three different tapes over the course of three weeks. Parents were asked to document how many times each tape was used (subjects were to listen to each tape at least three times), and to record any changes they observed in the child, during or after the listening sessions. Parents were also responsible for making an overall assessment of which tape the child liked best and which one seemed best for helping the child stay focused.

The purpose of the study was to evaluate reactions to three different patterns of Hemi-Sync tones (8 and 12 Hz; 8, 16, and 24 Hz; and 12 and 16 Hz) embedded in a musical score called

Heart Zones (The Institute of HeartMath, Boulder Creek, Calif.). The tapes were labeled simply A, B, and C, and were presented in random order to keep families "blind" to the treatment condition (i.e., they didn't know which frequency pattern they were listening to that week) and to rule out order effects (e.g., a tendency to favor the first or last tape, or to prefer one pattern only when it follows another). The parental assessments indicated a clear preference for the 12 and 16 Hz tape in this group of subjects. Included in the paper were parents' comments and observations supporting their assessments and illustrating the specific mood and/or behavioral changes they observed.

This study is important for two reasons. First, it provides practitioners and researchers with an empirical basis for selecting tapes for children with attentional problems. Second, it supports hypotheses derived from research on the brain-wave patterns ADD children tend to exhibit. Often, children with ADD demonstrate unusually slow brain-wave activity, with a higher than normal theta to beta ratio. Neurofeedback training for ADD typically focuses on decreasing theta activity (4 to 7 Hz) and increasing beta activity (12 to 18 Hz). Listening to Hemi-Sync tapes with tones in the beta range—the 12 and 16 Hz patterns preferred in Sornson's study—--may have the same type of effect on brain-wave activity, thereby facilitating one's ability to focus and concentrate.

Critical Elements of Research Design

As interesting and informative as the studies described above might be, the "gold standard" in research is the randomized, double-blind, placebo-controlled trial. What is it about controlled trials that makes scientists pay attention? Earlier we said that the quality of a study depends on two things: the detail and accuracy of the descriptions (the who, what, when, where, and why) and how successfully the study rules out alternative explanations for the results. The primary purpose of a randomized, double-blind, placebo-controlled trial is to rule out alternative explanations for observed effects.

Alternative explanations for positive results in studies that do not incorporate adequate controls include

a. *Maturation* - Subjects outgrew the problem or it resolved on its own.
b. *Attention effects* - Outcomes changed because attention was focused on them. Subjects were made more aware of problem behaviors by having them measured.
c. *Spurious treatment factors* - Changes were due to aspects of the treatment or treatment setting unrelated to the specific intervention under evaluation (e.g., a supportive relationship was established or the music was relaxing).
d. *Desire to please the investigator* - The patient wanted to please the therapist by meeting his or her performance expectations.

e. *Subject hopes and expectations* - The patient's own positive expectations or beliefs about the treatment (the placebo effect) produced the changes.
f. *Investigator bias* - The practitioner or researcher had a conscious or unconscious tendency to make observations and interpretations that were consistent with the desired result.
g. *Idiosyncrasies of the sample* - By chance or design, the treatment group consisted of people who were not representative of the group to whom you wanted to generalize.
h. *Chance* - Random fluctuations in behavior just happened to favor the treatment group and are unlikely to be replicated.

Although it may seem obvious to practitioners and patients that an observed improvement was due to the treatment, critics are unlikely to agree unless the research incorporates design factors that rule out such alternative explanations. This is the value of a well-designed, randomized, controlled trial.

So how do control groups and good research designs address the problem of causality? Basically, they do so by showing that another group, treated identically except for the chosen intervention, did not improve as much as the treatment group of interest. To demonstrate this you must attend to a number of factors in designing and conducting your study. These factors include

a. recruiting subjects based on well-defined inclusion and exclusion criteria;
b. assigning subjects randomly to groups, or matching groups according to variables deemed
c. likely to affect outcomes (e.g., intelligence, age, problem severity);
d. blinding subjects to the treatment condition, or including comparison groups that have an equal probability of success in the eyes of both subjects and investigators;
e. ensuring that all groups are treated identically except for the specific factor(s) you are trying
f. to evaluate;
g. collecting both pre- and post-test data;
h. using reliable and valid data collection instruments and methods;
i. conducting the appropriate statistical analyses; and
j. ensuring that you have adequate statistical power—a large enough sample size—to detect treatment effects in the statistical analyses.

Multiple-Group Controlled Trials

A paper published by Lane, Kasian, Owens, and Marsh (1998) provides an excellent and very relevant example of a double-blind, controlled trial. In this study, all subjects participated in three treatment sessions: a preliminary training session using a pink noise tape with no embedded tones, a thirty-minute session with a 1.5 and 4 Hz binaural-beat tape (delta/theta condition), and a thirty-minute session with a 16 and 24 Hz tape (beta condition). Analyses compared vigilance performance task scores across the two treatment conditions, as well as

changes in mood states before and after each session. Results showed that the subjects (twenty-nine adult volunteers) performed better on the vigilance task and experienced less fatigue and confusion when they listened to the beta binaural-beat tape. These findings supported the authors' hypotheses and are consistent with earlier research suggesting that beta tones and increased EEG activity in the beta frequency range are associated with enhanced attention and cognitive performance. Like Sornson's study, this research supports the proposition that Hemi-Sync tapes are a simple and effective way to affect brain-wave activity and states of consciousness.

Another approach to this study would have been to create three different treatment groups and compare results across groups. The crossover design selected by Lane et al., however, is much more efficient. When you do not expect effects from one treatment session to carry over to the next, a crossover study can essentially double your analysis sample, thus increasing the study's power with little additional expense.

Where to Start

If you are contemplating a study, you must first come up with a preliminary design. The next step is personally contacting fellow researchers or practitioners who have used similar designs, measures, and samples. Experience is a great teacher, and it is prudent to take advantage of what others have learned about the inevitable pitfalls and problems encountered in research. It is also wise to consult with a statistician or design expert prior to finalizing the study proposal to make sure that the sample size, outcome measures, and planned analyses are appropriate for your objectives. Someone at a local university may be willing to collaborate on the design and analysis components of your study in exchange for shared authorship on a paper or presentation. Finally, keep in mind that the larger goal, good research—whether you do a qualitative case study, a time-series analysis, or a controlled trial—will benefit the people we aim to serve, even if the proposed hypotheses are not supported. Every systematic evaluation of a promising new therapy enhances our ability to understand and optimize interventions for health and well-being.

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